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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/482,688	01/13/00	GARDINER	P 23925-4

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HM22/0726

EXAMINER

CHOI, F

ART UNIT	PAPER NUMBER
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1616

DATE MAILED:

07/26/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/482,688

Applicant(s)

GARDINER ET AL.

Examiner

Frank I Choi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,7,8,10-16,18-25,27-29,31-34,36-38,40-43,45-47,49-59 and 62-67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Continuation of Disposition of Claims: Claims pending in the application are 1,3-5,7,8,10-16,18-25,27-29,31-34,36-38,40-43,45-47,49-59 and 62-67.

DETAILED ACTION

Claim Objections

Claim 43 is objected to because of the following informalities:

“arginnie” should be “arginine”.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

Claim 63 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. It appears that alpha lipoic acid is not disclosed in the Specification and Applicant does not appear to have adequately explained where the addition of alpha lipoic acid does not constitute new matter.

Claims 5, 13, 15, 16, 20-24, 29, 38, 47, 53-57, 64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5, 29, 38, 47 recite the limitation "glucomannan". There is insufficient antecedent basis for this limitation in the claim.

Claims 13, 64 depend on one of claims 1-12, however, claims 2, 6, 9 are cancelled claims..

Claims 13, 15, 16, 64 contain trademarks or tradenames - WPI 97, Whey Peptides, WPC 80, and ION EXCHANGE whey protein – which render the claims indefinite as they identify the source and not the formulation which is subject to change by the manufacturer.

Claims 20-24, 53-57 contain the preamble “wherein the supplement comprises” but recite fewer compounds than the claim on which it is dependent which renders the claims indefinite as the supplement cannot contain fewer compounds. If Applicant wishes to modify the amount of certain compounds, Applicant should either recite all of the compounds of the supplement in their entirety but having different amounts which fall within the broad ranges of the claim on which is dependent, or, specifically recite the compounds without using the above preamble. For instance, “wherein the amount of glycosidal saponins is 50mg to 500mg”.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 8 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Schneider et al. (U.S. Pat. 5,902,829) for the reasons of record set forth in the prior Office Action and the further reasons below.

Schneider et al. was discussed in the prior Office Action and the same is incorporated herein.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

Examiner reminds Applicant that in a 102/103 inherency based rejection the Graham v. John Deere factors are inapplicable. As such, Applicant's 103 arguments do not overcome the rejection herein. In response to applicant's argument that the prior art is not enabling because it does not teach the same use, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). As such, since claims 1,8 are directed to compositions and the prior art expressly discloses a composition falling within the scope of Applicant's claims, the prior art meets the enablement requirement.

Claims 1, 8, 13-17, 58, 59, 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schneider et al. (U.S. Pat. 5,902,829) for the reasons of record set forth in the prior Office action and the further reasons below.

Schneider et al. was discussed in the prior Office Action and the same is incorporated herein.

In response to applicant's argument that the prior art does not teach the intended use, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Further, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Claims 1, 3, 8, 13-18, 25, 27, 34, 36, 37, 43, 45, 58 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Portman for the reasons of record set forth in the prior Office Action and the further reasons below..

Examiner reminds Applicant that in a 102/103 inherency based rejection the Graham v. John Deere factors are inapplicable. As such, Applicant's 103 arguments do not overcome the rejection herein. In response to applicant's argument that the prior art is not enabling because it does not teach the same use, a recitation of the intended use of the claimed invention must result

in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Claims 1, 3-5, 7, 8, 10-16, 18-25, 27-29, 31-34, 36-38, 40-43, 45-47, 49-59, 62-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Portman in view of Doi et al., Kim et al., Droge, Larner et al. and Jableck et al. for the reasons of record set forth in the prior Office Action in further view of Maxwell et al., Food Chem. News and Kolla et al. and the further reasons below.

Portman, Doi et al., Kim et al., Droge, Larner et al. and Jableck et al. were discussed in the prior Office Action and the same is incorporated herein.

Maxwell et al. teaches that exercise performance can be enhanced by augmenting endogenous nitric oxide with amino acids, including arginine, and folic acid and that taurine improves skeletal muscle metabolism (Column 2, lines 35-68, Column 3).

Food Chem. News teaches that pinitol enhances insulin function and lowers blood glucose (Abstract).

Kolla et al. teaches that lipoic acid increases work capacity and muscle strength (Abstract).

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on

combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Further, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Furthermore, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Herein, the difference between the prior art and the claimed invention is that the prior art does not expressly disclose using N-acetyl cysteine, glucomannan, taurine, folic acid or inositol compounds to increase muscle mass or strength. However, the prior art amply suggests the same as it is known that the activity of insulin is important in converting glucose into glycogen which is utilized by muscle cells for growth, proteins increase the activity of insulin, that glucomannan appears to have similar activity to insulin in lowering blood glucose levels, N-acetyl cysteine combined with insulin-like growth factors and amino acids is effective in increasing muscle growth, inositol compounds are effective in regulating insulin and are implicated in mechanisms from muscle hypertrophy due to exercise, that taurine increases muscle metabolism and arginine and folic acid increase exercise performance by increasing endogenous nitric oxide. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the composition would be

effective in increasing muscle mass, mimicking and/or enhancing the effect of insulin and increasing nitrogen oxide/nitrogen in the body.

In response to applicant's argument that Kim et al. and Lerner are nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Kim et al. is reasonably pertinent to the particular problem with which applicant was concerned in that applicant is concerned with substances which increase or promote nitric oxide. Further, Lerner is also reasonably pertinent to the particular problem with which applicant was concerned in that applicant is concerned with substances which increase the activity of insulin. Furthermore, Jablecki et al. is reasonably pertinent to the particular problem with which applicant was concerned in that applicant was concerned with muscle growth.

Finally, with respect to Doi, contrary to Applicant's arguments, Doi does not teach that glucomannan decreases the activity of insulin. Doi teaches that concurrent with the administration of glucomannan that blood immunoreactive insulin levels are depressed. This is consistent with the fact that glucomannan decreases blood glucose levels, as such, the body does not require as much insulin because the function of insulin has been mimicked by glucomannan.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Art Unit: 1616

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628.

FIC

July 24, 2001


JOHN PAK
PRIMARY EXAMINER
GROUP 1200

